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PRESS RELEASE

Hansa Biopharma completes enrollment in phase 2 study of imlifidase in Guillain-Barré Syndrome (GBS)

Lund, Sweden, 31 March 2023. Hansa Biopharma, "Hansa" (Nasdaq Stockholm: HNSA), a pioneer in enzyme technology for rare immunological conditions, today announced it has completed enrollment in its phase 2 study of imlifidase in Guillain-Barré Syndrome (GBS). Top-line data is expected to be shared during the second half of 2023.

Søren Tulstrup, President and CEO, Hansa Biopharma said, "This phase 2 study of imlifidase in GBS is an important next step in understanding the role of our antibody-cleaving enzyme technology in treating rare immunologic conditions. We remain fully committed to advancing the science and delivering innovative therapies to the many patients affected by severe immunologic conditions".

The phase 2 study in GBS is an open-label, single arm, multi-center study across the UK, France, and the Netherlands evaluating the safety, tolerability, and efficacy of imlifidase in GBS patients in combination with standard of care (SoC) intravenous immunoglobulin (IVIg). Enrolled patients have received imlifidase prior to SoC. Following database lock of the single arm study, efficacy parameters from patients treated with imlifidase and SoC will be compared with an external matched cohort from the International Guillain-Barré Syndrome Outcome Study (IGOS) database at the Erasmus Medical Centre, Rotterdam, Netherlands. The outcome of the comparative efficacy analysis between the two cohorts is expected to be shared during 2024.

Professor Shahram Attarian, Head of Department of Neuromuscular Diseases and ALS, Hopitaux Universitaires de Marseille (APHM), and International Coordinating Principal Investigator in the Phase 2 study, said "In the treatment of GBS, a timely diagnosis and treatment are crucial to reducing the severity of the symptoms and minimizing long term damage. With a unique treatment approach focused on rapidly and effectively reducing IgG levels, imlifidase represents a potentially new way to treat GBS patients".

GBS is a rare, acute, paralyzing, inflammatory disease of the peripheral nervous system affecting 1-2 in 100,000 people annually.[1] It is an aggressive neurological disease which rapidly and progressively weakens the extremities. It can lead to a severe paresis of the arms and legs, with around 25% of patients requiring mechanical ventilation for weeks or months and 20% unable to walk after six months.[2,3] With current standard of care, GBS is fatal in 3-7% of cases.[2,4]

In 2018, the U.S. Food and Drug Administration granted Orphan Drug Designation to imlifidase for the treatment of GBS.

More information about the trial is available at ClinicalTrials.gov under NCT03943589

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Notes to editors

About Hansa Biopharma

Hansa Biopharma is a pioneering commercial-stage biopharmaceutical company on a mission to develop and commercialize innovative, lifesaving and life-altering treatments for patients with rare immunological conditions. Hansa has developed a first-in-class immunoglobulin G (IgG) antibody-cleaving enzyme therapy, which has been shown to enable kidney transplantation in highly sensitized patients. Hansa has a rich and expanding research and development program based on the Company's proprietary IgG-cleaving enzyme technology platform, to address serious unmet medical needs in transplantation, autoimmune diseases, gene therapy and cancer. Hansa Biopharma is based in Lund, Sweden, and has operations in Europe and the U.S. The Company is listed on Nasdaq Stockholm under the ticker HNSA. Find out more at www.hansabiopharma.com.

References

1. McGrogan A, et al. Neuroepidemiology. 2009; 32(2):150-63
2. Fletcher D, et al. *Neurology*. 2000 27;54(12):2311-5
3. Van Doom P. *Presse Med.* 2013;42(6 Pt 2):e193-201.
4. Van den Berg B, et al., *Nat Rev Neurol.* 2014; Aug;10(8):469-82